

Norman C. Kleinberg  
 Theodore V. H. Mayer  
 William J. Beausoleil  
 HUGHES HUBBARD & REED LLP  
 One Battery Park Plaza  
 New York, New York 10004-1482  
 (212) 837-6000

*Attorneys for Defendant Merck & Co., Inc.*

UNITED STATES DISTRICT COURT  
 SOUTHERN DISTRICT OF NEW YORK

-----X		
IN RE:	:	
Fosamax Products Liability Litigation	:	1:06-md-1789 (JFK)
	:	
-----X		
<i>This Document Relates to:</i>	:	<b>ANSWER AND AFFIRMATIVE</b>
Cynthia Thibault and	:	<b>DEFENSES OF MERCK</b>
Robert Derostyne	:	<b>&amp; CO., INC.;</b>
v. Merck & Co., Inc. and	:	<b>DEMAND FOR JURY TRIAL</b>
Novartis Pharmaceuticals Corporation	:	
	:	
Case No: 1:08-cv-5544-JFK	:	
-----X		

Defendant, Merck & Co., Inc. (“Merck”), by and through its undersigned attorneys, hereby answers the Complaint. Merck denies all allegations set forth in the Complaint except to the extent such allegations are specifically admitted below. To the extent the allegations of any paragraph are directed to Novartis Pharmaceuticals Corporation (“Novartis”) or relate to ZOMETA® (“Zometa”), Merck is not required to respond to those allegations. To the extent a response is deemed necessary, Merck is without knowledge or information sufficient to form a belief as to such allegations.

## **I. PARTIES**

1. Merck is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 1.

2. Merck admits that it is a corporation organized under the laws of the State of New Jersey with its principal place of business located at One Merck Drive, Whitehouse Station, New Jersey. Except as expressly admitted herein, Merck denies the remaining allegations of Paragraph 2.

3. Merck admits that it is registered to do business in the State of Virginia, but is without knowledge as to what is meant by the phrase “regularly transacted,” so the remaining allegations in Paragraph 3 are denied.

4. Merck denies each and every allegation of Paragraph 4, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 4 inconsistent with that prescribing information and respectfully refers the Court to the Physicians’ Desk Reference (“PDR”) for FOSAMAX® for its actual language and full text.

5. Merck admits only that it distributed FOSAMAX® for prescription in accordance with its approved prescribing information and denies any allegations in Paragraph 5 inconsistent with that prescribing information. Merck respectfully refers the Court to the PDR for FOSAMAX® for its actual language and full text. Except as expressly admitted herein, Merck denies the remaining allegations of Paragraph 5.

6. Merck is without knowledge as to what is meant by the phrase “substantial revenue” so the allegations in Paragraph 6 are denied.

7. Merck is without knowledge as to what is meant by “consequences,” so the allegations in Paragraph 7 are denied.

8. Merck admits only that it distributed FOSAMAX® for prescription in accordance with its approved prescribing information. Merck denies the remaining allegations of Paragraph 8.

9. Merck denies each and every allegation of Paragraph 9, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information and denies any allegations in Paragraph 9 inconsistent with that prescribing information. Merck respectfully refers the Court to the PDR for FOSAMAX® for its actual language and full text.

10. Merck denies each and every allegation of Paragraph 10.

11. Merck denies each and every allegation of Paragraph 11.

12. Merck denies each and every allegation of Paragraph 12.

13. Merck denies each and every allegation of Paragraph 13.

14. – 28. The allegations of Paragraphs 14 – 28 are not directed at Merck and therefore, no response is required. To the extent a response is required, Merck states that as to all allegations against Novartis, all allegations relating to Zometa, and all allegations relating to Plaintiff’s use of Zometa, Merck is without knowledge or information sufficient to form a belief as to such allegations.

## **II. JURISDICTION AND VENUE**

29. The allegations of Paragraph 29 are conclusions of law to which no response is required. To the extent that a response is required, Merck denies each and every allegation of Paragraph 29.

30. Merck is without knowledge as to the allegations of Paragraph 30, but for jurisdictional purposes only, admits that the Plaintiffs seek in excess of \$75,000.

31. The allegations of Paragraph 31 are conclusions of law to which no response is required. To the extent that a response is required, Merck denies each and every allegation of Paragraph 31.

## **III. FACTUAL BACKGROUND**

32. Merck denies each and every allegation of Paragraph 32, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

33. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 33.

34. Merck admits only that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information and denies any allegations in Paragraph 34 inconsistent with that prescribing information. Merck also refers the Court to the prescribing information for Zometa and denies any allegations in Paragraph 34 with respect to Zometa inconsistent with that prescribing information. Merck denies the remaining allegations of Paragraph 34.

35. Merck admits only that some bisphosphonates contain nitrogen and some do not and that FOSAMAX® is a prescription medication approved by the FDA for

prescription in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 35 inconsistent with that prescribing information. Merck is without knowledge as to the allegations regarding Zometa, Aredia, Bondronat, Didronel, Bonefos, Loron, and Skelid. Merck respectfully refers the Court to the PDR for FOSAMAX® for its actual language and full text. Merck denies the remaining allegations of Paragraph 35.

36. Merck denies each and every allegation of Paragraph 36.

37. Merck denies each and every allegation of Paragraph 37.

38. Merck denies each and every allegation of Paragraph 38, except that Merck admits that the FDA drafted an “ODS Postmarketing Safety Review,” but respectfully refers the Court to said document for its actual language and full text.

39. Merck denies each and every allegation of Paragraph 39.

40. Merck denies each and every allegation of Paragraph 40.

41. Merck is without knowledge as to whether Plaintiff was prescribed FOSAMAX® or Zometa. Merck denies the remaining allegations in Paragraph 41.

42. Merck denies each and every allegation of Paragraph 42.

43. Merck denies each and every allegation of Paragraph 43.

44. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 44.

45. Merck denies each and every allegation of Paragraph 45.

46. Merck denies each and every allegation of Paragraph 46.

47. Merck denies each and every allegation of Paragraph 47.

48. Merck denies each and every allegation of Paragraph 48.

#### **IV. COUNTS**

##### **COUNT I: NEGLIGENCE**

49. Merck repleads its answers to Paragraphs 1 through and including 48, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

50. The allegations in Paragraph 50 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, the allegations are denied and Merck respectfully refers the Court to the relevant legal standard, including any conflict of law rules.

51. Merck denies each and every allegation of Paragraph 51, including each and every allegation contained in subparts (a) through (f).

52. Merck denies each and every allegation of Paragraph 52.

53. Merck denies each and every allegation of Paragraph 53.

54. Merck denies each and every allegation of Paragraph 54.

55. Merck denies each and every allegation of Paragraph 55.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs' Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

##### **COUNT II: STRICT LIABILITY**

56. Merck repleads its answers to Paragraphs 1 through and including 55, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

57. Merck denies each and every allegation of Paragraph 57, except that Merck admits that it manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

58. Merck denies each and every allegation of Paragraph 58, except that Merck admits that it manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information, states that it is without knowledge as to the condition of the FOSAMAX® or Zometa Plaintiff alleges she consumed.

59. Merck is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 59.

60. Merck denies each and every allegation of Paragraph 60.

61. Merck denies each and every allegation of Paragraph 61.

62. Merck denies each and every allegation of Paragraph 62.

63. Merck denies each and every allegation of Paragraph 63.

64. Merck denies each and every allegation of Paragraph 64.

65. Merck denies each and every allegation of Paragraph 65.

66. Merck denies each and every allegation of Paragraph 66.

67. Merck denies each and every allegation of Paragraph 67.

68. Merck denies each and every allegation of Paragraph 68.

69. Merck denies each and every allegation of Paragraph 69.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs' Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

**COUNT III: BREACH OF EXPRESS WARRANTY**

70. Merck repleads its answers to Paragraphs 1 through and including 69, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

71. Merck denies each and every allegation of Paragraph 71, and respectfully refers the Court to the FDA-approved prescribing information for FOSAMAX® for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck is without knowledge or information sufficient to form a belief as to the allegations regarding Novartis and Zometa in Paragraph 71.

72. Merck denies each and every allegation of Paragraph 72 directed against it. Merck is without knowledge or information sufficient to form a belief as to the allegations regarding Novartis and Zometa in Paragraph 72.

73. Merck denies each and every allegation of Paragraph 73.

74. Merck is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 74.

75. Merck denies each and every allegation of Paragraph 75.

76. Merck denies each and every allegation of Paragraph 76.

77. Merck denies each and every allegation of Paragraph 77.

78. Merck denies each and every allegation of Paragraph 78.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs' Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.



**COUNT IV: BREACH OF IMPLIED WARRANTY**

79. Merck repleads its answers to Paragraphs 1 through and including 78, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

80. Merck denies each and every allegation of Paragraph 80 directed against it, except that Merck admits that it manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information. Merck is without knowledge or information sufficient to form a belief as to the allegations regarding Novartis and Zometa in Paragraph 80.

81. Merck denies each and every allegation of Paragraph 81 directed against it, and respectfully refers the Court to the FDA-approved prescribing information for FOSAMAX® for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck is without knowledge or information sufficient to form a belief as to the allegations regarding Novartis and Zometa in Paragraph 81.

82. Merck denies each and every allegation of Paragraph 82.

83. Merck is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 83.

84. Merck denies each and every allegation of Paragraph 84.

85. Merck is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 85.

86. Merck is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 86.

87. Merck denies each and every allegation of Paragraph 87.

88. Merck denies each and every allegation of Paragraph 88.

89. Merck denies each and every allegation of Paragraph 89.

90. Merck denies each and every allegation of Paragraph 90.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs' Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

**COUNT V: FRAUDULENT MISREPRESENTATION - MERCK**

91. Merck repleads its answers to Paragraphs 1 through and including 90, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

92. Merck denies each and every allegation of Paragraph 92, including each and every allegation contained in subparts (a) and (b).

93. Merck denies each and every allegation of Paragraph 93.

94. Merck denies each and every allegation of Paragraph 94.

95. Merck denies each and every allegation of Paragraph 95.

96. Merck denies each and every allegation of Paragraph 96.

97. Merck denies each and every allegation of Paragraph 97.

98. Merck denies each and every allegation of Paragraph 98.

99. Merck denies each and every allegation of Paragraph 99.

100. Merck denies each and every allegation of Paragraph 100.

101. Merck denies each and every allegation of Paragraph 101.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs' Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

**COUNT VI: FRAUDULENT MISREPRESENTATION – NOVARTIS**

The allegations of this Count contained in Paragraph 102 through and including Paragraph 112 are directed solely at Novartis. Accordingly, Merck is not required to answer the allegations of these paragraphs. To the extent the Merck is required to answer such allegations, as to all allegations against Novartis, all allegations relating to Zometa, and all allegations relating to Plaintiff's use of Zometa, Merck is without knowledge or information sufficient to form a belief as to such allegations. To the extent that Paragraph 102 through Paragraph 112 includes allegations directed to Merck, Merck denies all such allegations.

**COUNT VII: FRAUDULENT CONCEALMENT - MERCK**

113. Merck repleads its answers to Paragraphs 1 through and including 112, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

114. Merck denies each and every allegation of Paragraph 114, including each and every allegation contained in subparts (a) and (b).

115. Merck denies each and every allegation of Paragraph 115.

116. Merck denies each and every allegation of Paragraph 116.

117. Merck denies each and every allegation of Paragraph 117.

118. Merck denies each and every allegation of Paragraph 118.

119. Merck denies each and every allegation of Paragraph 119.

120. Merck denies each and every allegation of Paragraph 120.

121. Merck denies each and every allegation of Paragraph 121.

122. Merck denies each and every allegation of Paragraph 122.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs' Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

**COUNT VIII: FRAUDULENT CONCEALMENT – NOVARTIS**

The allegations of this Count contained in Paragraph 123 through and including Paragraph 132 are directed solely at Novartis. Accordingly, Merck is not required to answer the allegations of these paragraphs. To the extent the Merck is required to answer such allegations, as to all allegations against Novartis, all allegations relating to Zometa, and all allegations relating to Plaintiff's use of Zometa, Merck is without knowledge or information sufficient to form a belief as to such allegations. To the extent that Paragraph 123 through Paragraph 132 includes allegations directed to Merck, Merck denies all such allegations.

**AFFIRMATIVE DEFENSES**

Discovery and investigation may reveal that any one or more of the following affirmative defenses should be available to Merck in this matter. Merck, therefore, asserts said affirmative defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Merck may withdraw any of these affirmative defenses as may be appropriate. Further, Merck reserves the right to amend its Answer to assert additional defenses, cross-claims, counterclaims, and other claims

and defenses as discovery proceeds. Further answering and by way of additional defense, Merck states as follows:

**FIRST AFFIRMATIVE DEFENSE**

Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations, doctrine of prescription, and/or is otherwise untimely.

**SECOND AFFIRMATIVE DEFENSE**

The Complaint fails to state a claim upon which relief can be granted.

**THIRD AFFIRMATIVE DEFENSE**

Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.

**FOURTH AFFIRMATIVE DEFENSE**

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening cause or causes.

**FIFTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiffs assert claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

**SIXTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiffs assert claims based upon an alleged failure by Merck to warn Plaintiffs directly of alleged dangers associated with the use of FOSAMAX®, such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warnings to the prescribing physician.

**SEVENTH AFFIRMATIVE DEFENSE**

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries or losses were caused in whole or in part by the contributory negligence of the allegedly injured Plaintiff.

**EIGHTH AFFIRMATIVE DEFENSE**

Any liability that might otherwise be imposed upon this Defendant is subject to reduction by the application of the doctrine of comparative fault.

**NINTH AFFIRMATIVE DEFENSE**

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries or losses were only sustained after Plaintiff knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any medicine or pharmaceutical preparation manufactured or distributed by Merck or other manufacturer.

**TENTH AFFIRMATIVE DEFENSE**

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

**ELEVENTH AFFIRMATIVE DEFENSE**

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiff's misuse or abuse of FOSAMAX®.

**TWELFTH AFFIRMATIVE DEFENSE**

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiffs' pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases, or illnesses, idiosyncratic reactions, subsequent medical conditions or natural courses of conditions for which this Defendant is not responsible.

**THIRTEENTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiffs rely upon any theory of breach of warranty, such claims are also barred for lack of timely notice of breach and/or lack of privity.

**FOURTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred in whole or in part under the applicable state law because FOSAMAX® was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

**FIFTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

**SIXTEENTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiffs seek punitive damages for the conduct which allegedly caused the injuries asserted in the Complaint, such an award would, if granted, violate Merck's state and federal constitutional rights.

**SEVENTEENTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiffs seek punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

**EIGHTEENTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiffs seek punitive damages, such claim is barred because FOSAMAX® and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

**NINETEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

**TWENTIETH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred in whole or in part because Merck provided legally adequate "directions or warnings" as to the use of FOSAMAX® and any other medicine or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

**TWENTY-FIRST AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred under Section 4, *et seq.*, of the Restatement (Third) of Torts: Products Liability.

**TWENTY-SECOND AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred under comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.



**TWENTY-THIRD AFFIRMATIVE DEFENSE**

There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of FOSAMAX®.

**TWENTY-FOURTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred in whole or in part by failure to mitigate damages.

**TWENTY-FIFTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred in whole or in part because Merck's conduct conforms with medical knowledge.

**TWENTY-SIXTH AFFIRMATIVE DEFENSE**

With respect to each and every cause of action, Plaintiffs are not entitled to recovery for strict liability because Plaintiffs cannot state claims founded in strict liability because, among other things, comments j and k to Section 402A of the Restatement (Second) of Torts relegates Plaintiffs' claims to a negligence cause of action.

**TWENTY-SEVENTH AFFIRMATIVE DEFENSE**

All activities of Merck as alleged in the Complaint were expressly authorized and/or regulated by a government agency. Therefore, Plaintiffs' claims pertaining to unfair or deceptive practices are barred.

**TWENTY-EIGHTH AFFIRMATIVE DEFENSE**

With respect to each and every cause of action, Plaintiffs are not entitled to recover because if the product involved was unsafe, which Merck denies, then it was unavoidably unsafe as defined in Restatement of Torts. The apparent benefits of the

product exceeded any apparent risk given the scientific knowledge available when the product was marketed.

**TWENTY-NINTH AFFIRMATIVE DEFENSE**

Merck's advertisements and labeling with respect to the products which are the subject matter of this action were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States, Virginia, and New York Constitutions.

**THIRTIETH AFFIRMATIVE DEFENSE**

The public interest in the benefit and availability of the product which is the subject matter of this action precludes liability for risks, if any, resulting from any activities undertaken by Defendant, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiffs' claims, if it is determined there is a risk inherent in the product which is the subject matter of this action, then such risk, if any, is outweighed by the benefit of the product.

**THIRTY-FIRST AFFIRMATIVE DEFENSE**

At all times relevant herein, any product which is the subject matter of this action processed and distributed by Merck in any state in the United States was manufactured and distributed in a reasonable and prudent manner based upon available medical and scientific knowledge and further was processed and distributed in accordance with and pursuant to all applicable regulations of the FDA.

**THIRTY-SECOND AFFIRMATIVE DEFENSE**

With respect to each and every purported cause of action, the acts of Merck were at all times done in good faith and without malice.

**THIRTY-THIRD AFFIRMATIVE DEFENSE**

To the extent there were any risks associated with the use of the product which is the subject matter of this action which Merck knew or should have known and which gave rise to a duty to warn, Merck at all times discharged such duty through appropriate and adequate warnings in accordance with federal and state law.

**THIRTY-FOURTH AFFIRMATIVE DEFENSE**

Plaintiffs have not sustained an ascertainable loss of property or money.

**THIRTY-FIFTH AFFIRMATIVE DEFENSE**

Plaintiffs have not suffered any actual injury or damages.

**THIRTY-SIXTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred under the doctrine of economic loss.

**THIRTY-SEVENTH AFFIRMATIVE DEFENSE**

This case is more appropriately brought in a different venue as defined in 28 U.S.C. §1404(a).

**THIRTY-EIGHTH AFFIRMATIVE DEFENSE**

This case is subject to dismissal and/or transfer to another venue pursuant to 28 U.S.C. §1406(a).

**THIRTY-NINTH AFFIRMATIVE DEFENSE**

This case is subject to dismissal or stay on the grounds of *forum non conveniens*.

**FORTIETH AFFIRMATIVE DEFENSE**

Plaintiffs' claims of fraud are not pleaded with the required particularity.

**FORTY-FIRST AFFIRMATIVE DEFENSE**

Plaintiffs cannot recover for the claims asserted because Plaintiffs have failed to comply with the conditions precedent necessary to bring this action and/or each particular cause of action asserted by Plaintiffs.

**FORTY-SECOND AFFIRMATIVE DEFENSE**

Plaintiffs' claims for breach of warranty are barred because Plaintiffs did not rely on such warranties and the claims are otherwise barred for lack of timely notice, lack of privity and/or because the alleged warranties were disclaimed.

**FORTY-THIRD AFFIRMATIVE DEFENSE**

An asymptomatic plaintiff lacks standing because she has suffered no damages and no injury-in-fact.

**FORTY-FOURTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiffs assert claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biologic Products, FDA Docket No. 2000N-1269 (January 24, 2006).

**FORTY-FIFTH AFFIRMATIVE DEFENSE**

The substantive law of Virginia applies to Plaintiffs' claims.

**FORTY-SIXTH AFFIRMATIVE DEFENSE**

Under Virginia law, Plaintiffs cannot assert a claim for strict liability.

**FORTY-SEVENTH AFFIRMATIVE DEFENSE**

Any claim for punitive damages cannot exceed the maximum permitted under VA Code Ann. § 8.01-38.1.

---

Inasmuch as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Merck to determine all of its legal, contractual and equitable rights, Merck reserves the right to amend and/or supplement the averments of its Answer to assert any and all pertinent liability defenses ascertained through further investigation and discovery.

Merck will rely on all defenses that may become available during discovery or trial.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs' Complaint with prejudice and awarding Merck its reasonable costs and disbursements, including reasonable attorneys' fees, together with such other and further relief that the Court may deem just and proper.

**JURY DEMAND**

Merck demands a trial by jury as to all issues so triable.

DATED: New York, New York  
July 24, 2008

Respectfully submitted,

HUGHES HUBBARD & REED LLP

By: /s/  
Norman C. Kleinberg  
Theodore V. H. Mayer  
William J. Beausoleil

One Battery Park Plaza  
New York, New York 10004-1482  
(212) 837-6000  
kleinber@hugheshubbard.com  
mayer@hugheshubbard.com  
beausole@hugheshubbard.com

*Attorneys for Defendant Merck & Co., Inc.*

CERTIFICATE OF SERVICE

I hereby certify that on this 24<sup>th</sup> day of July, 2008, I caused a copy of the foregoing ANSWER AND AFFIRMATIVE DEFENSES OF MERCK & CO., INC. to be served via first-class mail, postage prepaid, on the following:

CORY WATSON CROWDER & DEGARIS, P.C.  
Annesley H. DeGaris  
2131 Magnolia Avenue, Suite 200  
Birmingham, AL 35205

AND

PITTMAN, GERMANY, ROBERTS & WELSH, LLP  
Robert G. Germany  
410 S. President Street  
Jackson, MS 39201

The above addresses appeared on the prior papers in this action as the office address of the attorneys for Plaintiff.

Deponent is over the age of 18 years and not a party to this action.

I further certify under penalty of perjury that under the laws of the United States of America the foregoing is true and correct.

Executed on July 24, 2008

/s/  
Shawn McEnnis